

UNITED STATES DISTRICT COURT FOR THE
DISTRICT OF DELAWARE

ABBOTT LABORATORIES, an Illinois
corporation,

Plaintiff,

v.

BANNER PHARMACAPS INC., a Delaware
corporation,

Defendant.

Civil Action No.

COMPLAINT

Plaintiff Abbott Laboratories (“Abbott”), for its complaint against defendant Banner Pharmacaps Inc. (“Banner”), alleges as follows:

THE PARTIES

1. Abbott is a corporation organized under the laws of the State of Illinois, having its headquarters and principal place of business at Abbott Park, Illinois 60064.
2. Banner is a corporation organized under the laws of the State of Delaware, having its principal place of business at 4100 Mendenhall Oaks Parkway, Suite 301, High Point, NC 27265.

JURISDICTION AND VENUE

3. This Court has subject matter jurisdiction over this suit pursuant to 28 U.S.C. § 1331 and § 1338(a), as it arises under an Act of Congress relating to patents, Title 35, United States Code, §§ 1, *et seq.* Specifically, this action arises under the Hatch-Waxman Act, 35 U.S.C. § 271(e)(2).
4. This Court has personal jurisdiction over Banner.

5. Venue properly exists in this judicial district pursuant to 28 U.S.C. § 1391 and § 1400(b).

FACTUAL BACKGROUND

The '731 and '326 Patents

6. Abbott sells divalproex sodium tablets under the trademark Depakote[®]. Depakote[®] is used to treat epileptic seizures or convulsions, the manic episodes associated with bipolar disease, and for prophylaxis of migraine headaches.

7. The FDA approved Abbott's New Drug Application No. 18-723 to market Depakote[®] on March 10, 1983. As a result, Depakote[®] is included in the FDA's list of "Approved Drug Products With Therapeutic Equivalence Evaluations," also known as the "Orange Book." Approved drugs may be used as the basis of a later applicant's submission seeking FDA approval.

8. United States Patent No. 4,988,731 ("the '731 patent"), titled Sodium Hydrogen Divalproate Oligomer, issued on January 29, 1991. (A copy of the '731 patent is attached as Exhibit A.) The '731 patent expires January 29, 2008.

9. United States Patent No. 5,212,326 ("the '326 patent"), also titled Sodium Hydrogen Divalproate Oligomer, issued on May 18, 1993. (A copy of the '326 patent is attached as Exhibit B.) The '326 patent expires January 29, 2008.

10. Abbott is the owner of the '731 patent and the '326 patent and has the right to enforce both patents.

11. The claims of the '731 patent and the '326 patent have been interpreted by the United States Court of Appeals for the Federal Circuit, which has ruled that those patents are valid and enforceable and that they cover divalproex sodium. *See Abbott Labs v. TorPharm, Inc.*, 300 F.3d 1367 (Fed. Cir. 2002); *see also Abbott Labs v. TorPharm, Inc.*, 156 F. Supp. 2d

738 (N.D. Ill. 2001) (Norgle, J.); *Abbott Labs v. TorPharm, Inc.*, 309 F. Supp. 2d 1043 (N.D. Ill. 2004) (Posner, J, sitting by designation); *Abbott Labs v. Alra Labs*, 1997 WL 667796 (N.D. Ill. 1997) (Zagel, J.).

12. The '731 patent, '326 patent, and other patents are listed in the "Orange Book" in association with Depakote®.

Banner Notifies Abbott Regarding the Filing of New Drug Application 22-152

13. Abbott received a letter from Banner, dated October 9, 2007, which stated that (i) Banner had submitted New Drug Application No. 22-152 (the "Banner NDA") to the FDA, requesting approval to market a purported generic version of Depakote® in 125, 250, and 500 mg dosage strengths; (ii) the Banner NDA included a certification under 21 U.S.C. § 355(b)(2)(iv) of the Federal Food, Drug, and Cosmetic Act that the Banner NDA product would not infringe the '731 patent or the '326 patent; and (iii) Banner seeks FDA approval to market its product before the '731 patent and the '326 patents expire.

14. Banner attached to its October 9, 2007 letter a purportedly "Detailed Statement of the Factual and Legal Bases" for Banner's Paragraph IV Certification with regards to the '731 patent and the '326 patent. *See* 21 U.S.C. § 355(b)(3)(D)(ii). Banner stated its position in that document regarding whether its proposed product would infringe the '731 patent and the '326 patent, but did not argue that either patent is invalid or unenforceable.

15. Although Banner's October 9 letter describes the active ingredient in its proposed product as valproic acid, Banner did not select an approved valproic acid product as the reference listed drug for its FDA application. For instance, Abbott's Depakene® product contains valproic acid as its active ingredient, is listed in the Orange Book, and could be referenced by any company seeking to market a generic valproic-acid product. Instead, Banner suggests to FDA in

its application that the proper reference listed drug for its proposed product is Depakote[®], which contains divalproex sodium—not valproic acid—as its active ingredient.

16. Banner's business partner, Noven Pharmaceuticals, Inc. (which will be responsible for marketing and distributing Banner's proposed product upon FDA approval), has stated publicly that approval of Banner's proposed generic product is subject to any exclusivity periods applicable to Depakote[®]. (See Press Release, attached as Exhibit C.)

COUNT I: INFRINGEMENT OF THE '731 PATENT

17. Abbott repeats and incorporates by reference each and every allegation of paragraphs 1-16 as if fully set forth herein.

18. Under 35 U.S.C. § 271(e)(2), the submission of a NDA under 21 U.S.C. § 355(b)(2) for a drug claimed in a patent or for a drug use claimed in a patent is an act of infringement if the applicant seeks FDA marketing approval effective prior to the expiration of the patent.

19. Banner's submission of NDA No. 22-152 for approval to sell the product described therein in 125, 250, and 500 mg dosage strengths before the expiration of the '731 patent constitutes an act of infringement of that patent pursuant to 35 U.S.C. § 271(e)(2).

20. Abbott has no adequate remedy at law to redress this act of infringement.

COUNT II: INFRINGEMENT OF THE '326 PATENT

21. Abbott repeats and incorporates by reference each and every allegation of paragraphs 1-16 as if fully set forth herein.

22. Under 35 U.S.C. § 271(e)(2), the submission of an ANDA under 21 U.S.C. § 355(b)(2) for a drug claimed in a patent or for a drug use claimed in a patent is an act of infringement if the applicant seeks FDA marketing approval effective prior to the expiration of the patent.

23. Banner's submission of NDA No. 22-152 for approval to sell the product described therein in 125, 250, and 500 mg dosage strengths before the expiration of the '326 patent constitutes an act of infringement of that patent pursuant to 35 U.S.C. § 271(e)(2).

24. Abbott has no adequate remedy at law to redress this act of infringement.

PRAYER FOR RELIEF

WHEREFORE, Abbott prays for the following relief:

- a. a judgment that the '731 patent is infringed under 35 U.S.C. § 271(e)(2) by the filing of NDA No. 22-152;
- b. a judgment that the '326 patent is infringed under 35 U.S.C. § 271(e)(2) by the filing of NDA No. 22-152;
- c. an order declaring that NDA No. 22-152 cannot be approved earlier than the expiration date of Abbott's '731 patent;
- d. an order declaring that NDA No. 22-152 cannot be approved earlier than the expiration date of Abbott's '326 patent;
- e. an injunction preventing Banner, or any of its affiliates, from commercially manufacturing, selling, offering to sell, importing, or using the product described in NDA No. 22-152, or otherwise infringing one or more claims of the '731 patent during the life of the patent;
- f. an injunction preventing Banner, or any of its affiliates, from commercially manufacturing, selling, offering to sell, importing, or using the product described in NDA No. 22-152, or otherwise infringing one or more claims of the '326 patent during the life of the patent;
- g. such other and further relief as this Court may deem just and proper.

Dated: November 21, 2007

Of Counsel

Daniel E. Reidy

E-mail: dereidy@jonesday.com

James R. Daly

Email: jrdaly@jonesday.com

Jason G. Winchester

Email: jgwinchester@jonesday.com

Jeremy P. Cole

Email: jpcole@jonesday.com

Melissa B. Hirst

Email: mbhirst@jonesday.com

JONES DAY

77 West Wacker Drive, Suite 3500

Chicago, Illinois 60601-1692

(T): 312.782.3939

(F): 312.782.8585

Perry C. Siatis

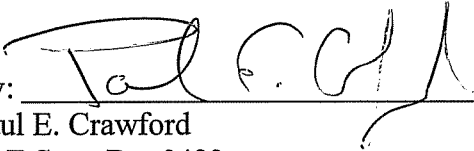
ABBOTT LABORATORIES

100 Abbott Park Road

Abbott Park, Illinois 60064-6034

Respectfully submitted,

CONNOLLY BOVE LODGE & HUTZ LLP

By: 
Paul E. Crawford

DE State Bar 0493

E-mail: pcrawford@cblh.com

CONNOLLY BOVE LODGE & HUTZ LLP

1007 N. Orange St.

P.O. Box 2207

Wilmington, DE 19899

(T) 302.658.9141

(F) 302.658.5614

Attorneys for Abbott Laboratories